

## REMARKS

### I. STATUS OF THE APPLICATION

Claims 1-23 were filed in the original application. During prosecution of the application, claims 1-23 were cancelled and claims 24-44 were added in the Amendment and Response to Office Action filed January 8, 2003. Claims 24-44 were cancelled and claims 45-71 were added in the Amendment and Response to Office Action filed May 1, 2003. Claims 69 and 70 were cancelled in the Amendment and Response to Final Office Action filed July 7, 2004. Claims 45-68, and 71 were cancelled, and claims 72-107 were added in the Amendment and Response to Office Action filed February 17, 2005. Claims 72-107 were rejected in the Final Office Action dated May 10, 2005.

In an Appeal Brief filed November 9, 2005 the Applicant appealed the Final Office Action of May 10, 2005. In the Decision on Appeal mailed July 31, 2006 the Board of Patent Appeals and Interferences reversed all of the Examiner's rejections. The Office Action mailed September 12, 2006 was made in Response to the Board's rejections. Claims 108-112 were added in the Amendment and Response to Office Action of September 12, 2006. Therefore, Claims 72-112 are currently pending.

In the Office Action dated June 18, 2007, the Examiner has made two rejections. The currently pending rejections are:

1. Claims 72-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acta Anaesthesiologica Scandinavica (Vol 39, page 139-141, 1995) (hereinafter "LaDu, 1995") and LaDu (Cellular and Molecular Neurobiology, Vol 11, No. 1, page 79-89, 1991 (hereinafter "LaDu, 1991") and Pharmacogenetics (Chapter 4, pages 309-326) (hereinafter "Pharmacogenetics") and Evans *et al.* (Science, Vol. 286, pages 487-491, October 1999) (hereinafter "Evans") in view of Hoon *et al.* (US Pat. 6,057,105, May 2, 2000) (hereinafter "Hoon") and Hacia (Nature Genetics Supplement, Vol. 21, pages 42047, January, 1999) (hereinafter "Hacia") and further in view of Ahern (The Scientist, Vol 9, No. 15, page 20, July

1995) (hereinafter, “Ahern”) and Anderson et al. (US Pat 6,267,722, July 31, 2001) (hereinafter “Anderson”). (Office Action of June 18, 2007, page 1.)

2. Claims 108-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller (Anesthesia, Vol. 2, pages 1323-1333, 1981) (hereinafter “Miller”), in view of Quane *et al.* (Human Molecular Genetics, Vol 3, No. 3, pages 471-476 (hereinafter “Quane”) or Acta Anaesthesiologica Scandinavica (Vol 39, page 139-141, 1995) (hereinafter “LaDu, 1995”) and LaDu (Cellular and Molecular Neurobiology, Vol 11, No. 1, page 79-89, 1991 (hereinafter “LaDu, 1991”) or Pharmacogenetics (Chapter 4, pages 309-326, IDS #201) (hereinafter “Pharmacogenetics”) and Evans *et al.* (Science, Vol. 286, pages 487-491, October 1999) (hereinafter “Evans”) or Poort *et al.* (Blood, vol 88 No. 10, page 3698-3703, 1996) (hereinafter “Poort”) and further in view of Hoon *et al.* (US Pat. 6,057,105, May 2, 2000) (hereinafter “Hoon”) and Hacia (Nature Genetics Supplement, Vol. 21, pages 42047, January, 1999) (hereinafter “Hacia”) and further in view of Ahern (The Scientist, Vol 9, No. 15, page 20, July 1995) (hereinafter, “Ahern”) and Anderson et al. (US Pat 6,267,722, July 31, 2001) (hereinafter “Anderson”) as applied to claims 72-107 and further in view of the specification (hereinafter “Specification”) (Tables 1-4) . (Office Action of June 18, 2007, pages 10-11.)

## **II. STATUS OF THE REJECTION**

### **A. Claims 72-107 are not Obvious**

A *prima facie* case of obviousness requires the Examiner to cite to a reference which a) discloses all the elements of the claimed invention, b) suggests or motivates one of ordinary skill in the art to combine the claim elements to yield the claimed invention, and c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of these three requirements negates a finding of

a *prima facie* case and, without more, entitles the Applicant to allowance of the claims in issue. (MPEP).

**1. Examiner's Combination of References Does Not Teach All Elements of the Claims**

**a. The Examiner has Failed to Establish the Obviousness of Claims 72-105, and**

Contrary to the Examiner's assertion, the Examiner's combination of references fails to teach all elements of the claims.

For example, none of the Examiner's references, alone or in combination, teach or suggest a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents. In its Decision on Appeal, the Board of Patent Appeals and Interferences expressly considered this element of claim 72:

"Finally, the kit defined by claim 72 comprises "a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents."" (Decision on Appeal, page 5). (Emphasis added.)

Accordingly, the Board of Patent Appeals and Interferences concluded:

"In our view, these disclosures (*i.e.*, of the Specification) reasonably support the concept of combining reagents for detecting variant alleles with a computer program to analyze data indicating the presence or absence of such variant alleles." (Decision on Appeal, page 8). (Emphasis added.)

In the Office Action of June 18, 2007 the Examiner improperly dismisses this element of the claims that has previously been expressly recognized and accepted by the Board of Appeals and Interferences:

"Further, with regard to the limitation that the kits contain instructions for using said kit for generating said perioperative genomic profile for said subject, the

inclusion of instructions is not considered to provide a patentable limitation on the claims. See *In re Ngai*, 367 F.3d 1336, 70 U.S.P.Q. 2d 1862 (Fed. Cir. 2004) (holding that an inventor could not patent known kits by simply attaching new set of instructions to that product).” (Office Action of September June 18, 2007 page 2).

In this assertion the Examiner has made a number of legal errors.

First, the Board of Appeals and Interferences has already considered the Examiner’s arguments with regard to *In re Ngai* (See, for example, Examiner’s Answer mailed December 30, 2005, pages 18-22), and has found the Examiner’s assertions non-persuasive. The Examiner is bound by the Board’s decision.

Second, at the time of its Decision the Board of Patent Appeals and Interferences was in possession of a detailed consideration of *In re Ngai* in the Appellant’s Reply Brief filed by the Applicant on March 3, 2006. In its Decision on Appeal of July 31, 2006, the Board of Patent Appeals and Interferences does not rebut a single point or issue raised by the Applicant with regard to the inapplicability of *In re Ngai* to the prosecution of the present application.

Third, the kits of the claimed invention are not “known kits”. This point was brought to the Examiner’s attention in the Amendment and Response to Office Action Dated September 12, 2006, page 12. The present Office Action of June 18, 2007 is unresponsive to this fact.

Fourth, the Examiner has never indicated where such kits (*e.g.*, kits with “reagents configured such that when exposed to a sample containing target nucleic acid from a perioperative subject, said subject being a patient scheduled for a surgical procedure that has not yet completed said surgical procedure, are sufficient to detect the presence or absence of variant alleles in two or more genes associated with two or more conditions selected from the group consisting of *BChE*, *CYP2D6*, *F5*, *F2*, *CACNAIS*, *MTHFR*, *MTR*, *MTRR*, *CBS*, *TNF $\alpha$*  and *TNF $\beta$*  so as to generate a genomic profile for use in selecting a perioperative course of action for said subject”) are to be found in the Examiner’s references, either alone or in combination.

Fifth, the Examiner confuses the printed matter instructions of *In re Ngai* with a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents of the claims. As pointed out to the Examiner in the Appellant's Brief "Contrary to the Examiner's misinterpretation, *In re Ngai* does not address, consider or even mention computers, computer programs, computer programs comprising instructions, or computer analysis of data." (Appellant's Brief, page 37) (Emphasis in original). As pointed out to the Examiner (Appellant's Brief, page 38), computer instructions which direct a processor to analyze data for generating a perioperative genomic profile for a subject as claimed, qualify as statutory subject matter because storage of the computer instructions turns a computer readable medium into a functional component which directly cooperates with the processor. Computer instructions cause computer functions to occur, and are therefore inarguably functional components of the computer system. These facts have been acknowledged by the Board of Appeals and Interferences, and are uncontested in the Office Action of June 18, 2007.

The Examiner's addition of Anderson to the Examiner's combination of 7 other references does not remedy these multiple defects. For example, Anderson does not teach or suggest a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents configured such that when exposed to a sample containing target nucleic acid from a perioperative subject, the subject being a patient scheduled for a surgical procedure that has not yet completed the surgical procedure, are sufficient to detect the presence or absence of variant alleles in two or more genes associated with two or more conditions selected from the group consisting of *BChE*, *CYP2D6*, *F5*, *F2*, *CACNAIS*, *MTHFR*, *MTR*, *MTRR*, *CBS*, *TNF $\alpha$*  and *TNF $\beta$*  so as to generate a genomic profile for use in selecting a perioperative course of action for said subject.

For at least these reasons, and as accepted by the Board of Appeals and Interferences, "a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents" (*i.e.*, not merely any computer program that the Examiner is able to locate in the prior art) is a proper and statutory element of claims 72-105. None of the Examiner's references, alone or in combination, teach or suggest this element. In turn, none of the Examiner's references,

alone or in combination, teach or suggest the limitation “a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents to indicate an anesthesia treatment course of action.” (Independent claim 84.) As well, none of the Examiner’s references, alone or in combination, teach or suggest the limitation “a computer program comprising instructions which direct a processor to analyze data derived from use of said reagents to indicate a surgical treatment course of action.” (Independent claim 101.) These missing elements were pointed out to the Examiner in the Amendment and Response to Office Action of September 12, 2006, page 14. The Office Action of June 18, 2007 is unresponsive to these facts.

As well, in the Office Action of June 18, 2007 the Examiner fails to address elements of dependent claims that are missing from the Examiner’s combinations of references. For example, in order to establish *prima facie* obviousness, the Examiner must point to a reference, or combination of references, that teaches or suggests a computer program with software that analyzes data from the kit of the claimed invention, and generates, for example, recommendations for treatment options based on the presence or absence of variant alleles in *BChE*, *CYP2D6*, *F5*, *F2*, *CACNAIS*, *MTHFR*, *MTR*, *MTRR*, *CBS*, *TNF $\alpha$*  and *TNF $\beta$* . The Examiner has never identified such a computer program in the cited references taken alone, or in combination. Nowhere in the Examiner’s cited references is knowledge of variant alleles in two or more genes selected from the group consisting of *BChE*, *CYP2D6*, *F5*, *F2*, *CACNAIS*, *MTHFR*, *MTR*, *MTRR*, *CBS*, *TNF $\alpha$*  and *TNF $\beta$*  combined to indicate an anesthesia treatment course of action (claim 84), a surgical treatment course of action (claim 101), a specific clinical pathway of medical intervention (claim 106), or a specific clinical pathway or anesthesia intervention (claim 107). None of the Examiner’s references teach or suggest how to perform, or even whether to perform, the combination of data from the claimed variant alleles, and translation of this data into a subject-specific treatment course of action.

Nor do the Examiner’s cited references teach or suggest a computer program that directs the fate of the genetic data according to the subject’s preference (claim 82), or that directs a user to a specific perioperative clinical pathway for a subject (claim 83). None of the Examiner’s references teach or suggest kits with reagents sufficient to detect variant alleles in *F5*, *F2*, *CACNAIS*, *MTR*, *MTRR*, and *CBS*. What is missing from the

Examiner's references is a disclosure of, for example, primers and probes specific to these genes and these alleles. None of the Examiner's references, alone or in combination, teach or suggest kits sufficient to detect the presence or absence of variant alleles in two or more genes, or even kits sufficient to detect the presence or absence of variant alleles in a single gene.

Ahern teaches kits for, for example: expression of proteins from cloned genes; for labeling DNA or RNA probes with radioisotopes or fluorescent tags; for labeling oligonucleotides by conjugation with alkaline phosphatase; for small-scale purifications; for isolating cells from whole blood for cytotoxicity assays; for painting chromosomes with fluorescent dyes; for cryopreserving mouse embryos; and for signal transduction research. Ahern does not teach or suggest kits sufficient to detect variation in one gene. Ahern does not teach or suggest kits sufficient to detect variation in two genes. Ahern does not teach or suggest kits sufficient to detect variation in two or more genes selected from a group of genes, or in two or more genes associated with two or more conditions selected from the group consisting of *BChE*, *CYP2D6*, *F5*, *F2*, *CACNA1S*, *MTHFR*, *MTR*, *MTRR*, *CB*, *TNF $\alpha$*  and *TNF $\beta$* . These missing elements were pointed out to the Examiner in the Amendment and Response to Office Action of September 12, 2006, page 15. The Office Action of June 18, 2007 is unresponsive to these facts.

To the extent that Ahern contemplates characterization of DNA, Ahern teaches directly away from the use of such kits:

"Some tasks ... such as constructing genomic libraries, designing primer sets for sequencing, or synthesizing nucleic acids or peptides ... are so daunting that for many scientists it makes more sense to hire out." (Ahern, page 5). (Emphasis added).

Because the Examiner's references individually, and in combination, fail to teach all elements of claims 72-105, and indeed teach away from one another, the Examiner has failed to establish the *prima facie* obviousness of the claims. In view of the above, the Applicant respectfully requests that this rejection be withdrawn.

**b. The Examiner has Failed to Establish the Obviousness of Claims 106 and 107**

Contrary to the Examiner's assertion, the Examiner's combination of references fails to teach all elements of the claims. For example, none of the Examiner's references teach or suggest kits with component sufficient to detect variant alleles in *F5*, *F2*, *CACNA1S*, *MTR*, *MTRR*, and *CBS*. What is missing from the Examiner's references is a disclosure of, for example, primers and probes specific to these genes. As well, none of the Examiner's references teach or suggest kits with component parts sufficient to detect the presence or absence of variant alleles in each of *BChE*, *CYP2D6*, *F5*, *F2*, *CACNA1S*, *MTHFR*, *MTR*, *MTRR*, *CBS*, *TNF $\alpha$*  and *TNF $\beta$*  of claims 111 and 112.

Moreover, none of the Examiner's references, alone or in combination, teach or suggest kits sufficient to detect the presence or absence of variant alleles in two or more genes, or even kits sufficient to detect the presence or absence of variant alleles in a single gene.

Ahern teaches kits for, for example: expression of proteins from cloned genes; for labeling DNA or RNA probes with radioisotopes or fluorescent tag; for labeling oligonucleotides by conjugation with alkaline phosphatase; for small-scale purification; for isolating cells from whole blood for cytotoxicity assay; for painting chromosomes with fluorescent dyes; for cryopreserving mouse embryos; and for signal transduction research. Ahern does not teach or suggest kits sufficient to detect variation in one gene, in two genes, or in two or more genes associated with two or more conditions selected from the group consisting of *BChE*, *CYP2D6*, *F5*, *F2*, *CACNA1S*, *MTHFR*, *MTR*, *MTRR*, *CB*, *TNF $\alpha$*  and *TNF $\beta$* .

To the extent that Ahern contemplates characterization of DNA, Ahern teaches directly away from the use of such kits:

"Some tasks ... such as constructing genomic libraries, designing primer sets for sequencing, or synthesizing nucleic acids or peptides ... are so daunting that for many scientists it makes more sense to hire out." (Ahern, page 5). (Emphasis added).



These missing elements were pointed out to the Examiner in the Amendment and Response to Office Action of September 12, 2006, pages 16-17. The Office Action of June 18, 2007 is unresponsive to these facts. Because the Examiner's references individually, and in combination, fail to teach or suggest all elements of claims 106-107, the Examiner has failed to establish the *prima facie* obviousness of the claims. In view of the above, the Applicant respectfully requests that this rejection be withdrawn.

**2. The Examiner's References Does Not Provide a Suggestion or Motivation to Combine the Recited Elements**

In the Office Action of June 18, 2007 the Examiner argues:

"The ordinary artisan would have been motivated to have packaged reagents needed to screen individuals to determine the genetic composition of the individuals to provide individualized diagnosis and to avoid any fatal reaction to the anesthesia in a quick and efficient cost effective kit." (Office Action of June 18, 2007, page 7).

And:

"Thus, the ordinary artisan would have been motivated to have packaged the primers, probes, and reagents of Acta Anaesthesiologica Scandinavica, LaDu, Pharmacogenetics, or Evans and Hacia and Hoon which are necessary for determining the genotypes of BchE and CYP2D6 which are associated [with] poor reactions to anesthesia into a kit, as taught by Ahern for the express purpose of saving time and money and included a computer program taught by Anderson for the digitization, integraton and convenience of patient information, and risk index." (Office Action of June 18, 2007, page 8).

And:

“The teaching suggestion and motivation may be the common sense of those skilled in the art would employ. Thus, as is here, the ordinary artisan would be motivated to have gathered the reagents necessary for determining alleles associated with poor outcomes to surgery into a kit for the benefits of a kit.”  
(Office Action of June 18, 2007, pages 9-10.)

At multiple points in the Office Action of June 18, 2007 the Examiner acknowledges the advantages of the presently claimed invention, and identifies one of ordinary skill in the art as a clinician. Moreover, the Examiner expressly recognizes an anesthesiologist as one of ordinary skill in the art:

“The ordinary artisan would have recognized that the art provides a large number of single nucleotide polymorphisms or other variations which are indicative of conditions. The benefit of screening individuals for several of these prevalent mutations which are related to surgery would have allowed the anesthesiologist to determine whether plausible substitutes may be provided to patients which would not cause these conditions to arise.” (Office Action of June 18, 2007, pages 7-8.)  
(Emphasis added.)

And:

“Combining more than one screening method to determine the genomic profile of a patient would have provided the anesthesiologist with a more complete picture of the patients genetic make-up.” (Office Action of June 18, 2007, page 8.)  
(Emphasis added.)

Accordingly, the Applicant submits that the Examiner’s speculations and conclusory statements regarding the motivation and common sense of the ordinary artisan anesthesiologist to combine the claim elements to yield the claimed invention are in error.

The Applicant herewith submits the Declaration of Dr. Kirk Hogan. In his Declaration Dr. Hogan explains that prior to the perioperative genomic profile kits of the

presently claimed invention, anesthesiologists of ordinary skill were not aware of, and did not use, kits for genomic analysis of single or multiple polymorphisms, genes or diseases. Dr. Hogan explains that:

“While the anesthesiologist of ordinary skill has for many decades recognized that inborn predispositions are significant contributors to morbidity and mortality in the interval surrounding surgery, anesthesiologists of ordinary skill could not have combined the claimed elements because they lacked the requisite appreciation of the technical knowledge to arrive at the perioperative genomic profile kits of the presently claimed invention as a solution to the problems addressed by the presently claimed invention.” (Declaration of Kirk Hogan M.D. Under 37 C.F.R. 1.132, page 2.)

In proffering an *prima facie* case of obviousness, the Examiner must provide a basis for combining alleged art references and their elements. The requirement that the Examiner make a showing of a suggestion, teaching or motivation to combine the prior art references is “an essential evidentiary component of an obviousness holding.”<sup>1</sup>

The Applicant submits herewith the Declaration of Dr. Douglas Baird Coursin. In his Declaration, Dr. Coursin explains that there was no suggestion or teaching in the prior art for periperative genomic profiles. Dr. Coursin further explains the long felt and unmet need for this solution to the problem of inborn predispositions to complications during anesthesia and surgery, and the unexpected success of the technology. Dr. Coursin is one of the leading anesthesiologists in the country, and has been for many years. Dr. Coursin explains that skilled artisans, such as anesthesiologists, have as a primary mission to solve the problem solved by the present invention. Yet even with this long-felt need and years of searching by innumerable practitioners, no one solved this long-felt need using the approach of the present invention.

In a situation like the present one, there may be no better evidence of non-obviousness than the failure of an entire field to solve their primary problem, even with a wealth of information and technology known in the literature. As Dr. Coursin notes:

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<sup>1</sup> *C.R. Bard, Inc. v. M3 Sys. Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998).

“However, if the perioperative genomic profiles of the present patent application were obvious, the ordinary practitioner would have arrived at the claimed combinations in view of long felt and unmet needs to directly identify genetic predispositions before, during and after surgery. No person having ordinary skill in the art, or even extraordinary skill, took this step before the claimed invention was made.” (Declaration of Douglas Baird Coursin, M.D. Under 37 C.F.R. 1.132, page 3.)

The field failed to realize the solution because the solution was not obvious to these skilled artisans. These skilled artisans would not, and did not, see the combination the Examiner proposes that they should have and would have seen.

The United States Patent and Trademark Office’s rejection is based on hindsight knowledge of the invention wherein the Examiner has assumed what skilled artisans *should have* thought of the invention in view of numerous disparate pieces of prior art. In making the rejection, the Examiner, who is not one of skill in the art and who is in possession of hindsight knowledge of the invention, has *seen* an invention that the entire world of skilled artisans, focused for many years on the exact problem solved by the invention, had failed to see. Artisans, of ordinary and extraordinary skill in the field, who have devoted their careers to solving this problem, failed to put together the Examiner’s combination of references, and failed to solve the problem. The only logical explanation is that the invention is non-obvious.

Notably missing from the Examiner’s rejection is placement in the hands and minds of skilled artisans of: 1) the prior art of record (is this the type of work one skilled in the art would have reviewed in assessing the problem?); and 2) the mental and experimental process for modifying the art to arrive at the invention (even if they would have reviewed the cited art, would they have put the pieces together and modified the pieces appropriately?). At no point does the Examiner provide evidence of the handling of the references in the hands and minds of the appropriate skilled artisan. Regardless, even if the Examiner had done this, the evidence of long-felt but unresolved need

demonstrates that skilled artisan did not, and would not, arrive at the invention. If it were obvious, they would have done it years before the filing of the present application.

The Supreme Court specifically states:

“Often it will be necessary . . . to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. To facilitate review, this analysis should be made explicit.” (*KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. \_\_\_, 127 S. Ct. 1727 (2007).) (Emphasis added.)

The Applicant asserts that in formulating a rejection under 35 U.S.C. 103(a) based upon a combination of 8 prior art elements (vs. 2 prior art references in *KSR v. Teleflex*), the Examiner has clearly failed to identify the reason why a person of ordinary skill in the art would have made the combination in the manner claimed. In making such a reconstruction, the Examiner may only take into account the common knowledge which was within the level of ordinary skill at the time the claimed invention was made, and may not include, as here, knowledge gleaned only from the Applicant’s disclosure or unsupported assumptions about the mindset of the skilled artisan. (See *In re McLaughlin*, 443 F/2d 1392, 170 USPQ 209 CCPA, 1971.) The determination of whether a combination is a predictable variation of the prior art must be evaluated from the perspective of the person of ordinary skill in the art at the time claimed invention was made. Dr. Hogan’s and Dr. Coursin’s Declarations provide material evidence that Examiner’s speculations regarding the level of ordinary skill are in error.

In the Office Action of June 18, 2007 the Examiner notes:

“Finally, Ahern teaches reagent kits offer scientists good return on investment. Ahern teaches kits save time and money because the kits already come prepared.” (Office Action of June 18, 2007, page 5)

In relying upon these arguments to support a *prima facie* case of obviousness, the Examiner has made a number of errors. First, The Examiner's acknowledgment of the benefits of the claimed invention made after the Examiner was in possession of the Specification and claims does not, and cannot, substitute for substantial evidence of what an artisan of ordinary skill would or would not have been motivated to do at the time the invention was made. To the contrary, the in the Office Action of June 18, 2007 the Examiner improperly persists in asserting new standards of the ordinary artisan's motivation to combine references *i.e.*, to "save time and money", and "to avoid any fatal reaction."

The Applicant reminds the Examiner that the Examiner's standards are not those recognized by the law and by the CAFC. In *In re Sang Su Lee* the Court of Appeals for the Federal Circuit expressly prohibits this kind of substitution of the benefits of an invention for objective evidence of an invention's obviousness by the Patent and Trademark Office.<sup>2</sup> On multiple occasions in the prosecution of the present application the Examiner has had the opportunity to address this holding, and has never done so.

Clearly, the Examiner's improper combination of references, and failure to respond to numerous facts in the Applicant's Amendment and Response to the Office Action of September 12, 2006, preclude a finding of *prima facie* obviousness of the claims. In view of the above, the Applicant respectfully requests that this rejection be withdrawn.

#### **B. Claims 108-112 Are Not Obvious**

A *prima facie* case of obviousness requires the Examiner to cite to a reference which a) discloses all the elements of the claimed invention, b) suggests or motivates one of ordinary skill in the art to combine the claim elements to yield the claimed invention, and c) provides a reasonable expectation of success should the claimed combination be carried out. Failure to establish any one of these three requirements negates a finding of a *prima facie* case and, without more, entitles the Applicant to allowance of the claims in issue. (MPEP)

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<sup>2</sup> *In Re Sang Su Lee*, 277 F.3d 1338, 1341, USPQ2d 1430, 1433. (Fed. Cir. 2002).

The Applicant respectfully notes that the Examiner's references fail to disclose all elements of the claimed invention for at least the reasons cited under II.A. above with reference to the base claims upon which they depend. Thus, the Examiner's reference fails to establish *prima facie* obviousness of the claims. In view of the above, the Applicant respectfully requests that this rejection be withdrawn.

### III. CONCLUSION

It is respectfully submitted that Applicant's claims as should be passed into allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: December 18, 2007

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